

## REMARKS

The Office Action mailed 26 March 2010, has been received and its contents carefully noted. Claims 1–35 were pending, claims 6–35 were withdrawn, and claims 1–5 were rejected. By this amendment, claims 1, 3–5, and 21 are amended, claims 2, 6–20, and 26–35 are canceled, and claim 36 is newly added. Support may be found in the specification and the claims as originally filed. Claim 1 has been amended to define the diabetogenic epitope as EEQLRELRRQ (SEQ ID NO:1). Thus, claim 2 has been cancelled as being superfluous. The preambles of claims 3–5 have been amended to contain proper antecedent basis. New claim 6 has been added to define the amino acid sequence as SEQ ID NO:4 which is supported by Table 2 and SEQ ID NO:4. Claim 21 has been amended to depend on claim 1. No statutory new matter has been added. Therefore, reconsideration and entry of the claims as amended are respectfully requested.

## Sequence Listing

The Examiner asserted that the Sequence Listing does not comply with the requirements as it does not list the Inventors.

Applicants respectfully submit a Substitute Sequence Listing herewith (using EFS-web). Therefore, the objection to the Sequence Listing may be properly withdrawn.

In connection with the Substitute Sequence Listing submitted herewith, the undersigned hereby states that:

1. In accordance with 37 C.F.R. 1.825(a), the Substitute Sequence Listing does not contain new matter.
2. In accordance with 37 C.F.R. 1.825(b), the content of the attached paper copy and the attached computer readable copy of the Substitute Sequence Listing are the same.
3. All statements made herein are true and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of

the United States Code and that such willful false statements may jeopardize the validity of the application or any patent resulting therefrom.

### **Rejection under 35 U.S.C. 112, first paragraph**

The Examiner rejected claims 1, 3, 4, and 5 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner deemed that the specification does not disclose an adequate number of diabetogenic epitopes or the structure and function of a diabetogenic epitope.

Applicant has amended claim 1 to include the subject matter of claim 2, specifically, the diabetogenic epitope identified as SEQ ID NO:1. Accordingly, it is believed that the amendment obviates the Examiner's objection.

Therefore, the rejection under 35 U.S.C. 112, first paragraph, may be properly withdrawn.

### **Rejection under 35 U.S.C. 102(b)**

The Examiner rejected claims 1, 2 and 4 under 35 U.S.C. 102(b) as being anticipated by MacFarlane. Specifically, the Examiner deemed that MacFarlane discloses a Glb1 isoform, the protein expressed from clone WP5212, comprising the EEQLRELRRQ amino acid sequence of SEQ ID NO:1.

Applicant respectfully disagrees and traverses this rejection based on the present claims as amended. Specifically, MacFarlane discloses a DNA clone termed WP5212 that exhibits 90% homology over 1387 base pairs to *Triticum aestivum* (wheat) storage protein (Glb 1) gene and exhibits 80% identity over 642 amino acids to *T. aestivum* (wheat) storage protein (GenBank accession number AAA34269.1) (see page 55, Table 1, and the paragraph at page 58 beginning "Nucleotide and translated BLAST searches of GenBank...").

Applicants respectfully submit that MacFarlane does not disclose an amino acid sequence comprising a diabetogenic epitope defined by EEQLRELRRQ (SEQ ID NO:1). In addition, the *T. aestivum* (wheat) storage protein defined by GenBank accession number AAA34269.1 in MacFarlane does not disclose or suggest a diabetogenic epitope defined by EEQLRELRRQ (SEQ ID NO:1). In fact, there is no disclosure in MacFarlane that would lead one of ordinary skill in the art to an amino acid sequence comprising a diabetogenic epitope defined by EEQLRELRRQ

(SEQ ID NO:1) or the amino acid sequence defined by SEQ ID NO:4. Accordingly, Applicants respectfully submit that the claims, as amended, are novel.

Therefore, the rejection under 35 U.S.C. 102(b) may be properly withdrawn.

### **Rejections under 35 U.S.C. 103(a)**

The Examiner rejected claim 3 under 35 U.S.C. 103(a) as being unpatentable over MacFarlane in view of US 6,803,221. The Examiner also rejected claims 4 and 5 as being unpatentable over MacFarlane in view of US 6,927,041.

As set forth above, MacFarlane does not teach or suggest an amino acid sequence comprising a diabetogenic epitope defined by EEQLRELRRQ (SEQ ID NO:1). The deficiencies of MacFarlane are not alleviated by U.S. Patent 6,803,221 and U.S. Patent 6,927,041, alone or in combination. Specifically, none of the cited documents, alone or in combination, teaches or suggests an amino acid sequence comprising a diabetogenic epitope defined by EEQLRELRRQ (SEQ ID NO:1). Thus, the instant claims are unobvious.

Therefore, the rejection under 35 U.S.C. 103(a) may be properly withdrawn.

### **Request for Rejoinder**

Applicants have amended claim 21 to depend directly on claim 1. As such, Applicants respectfully request rejoinder of claims 21 and 24–25.

### **Request for Interview**

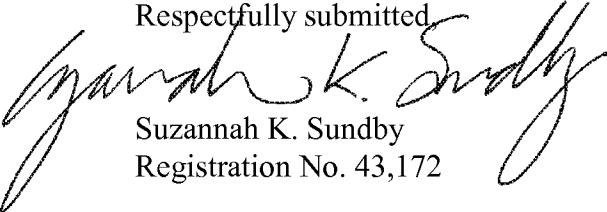
Either a telephonic or an in-person interview is respectfully requested should there be any remaining issues.

## CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Therefore, it is respectfully requested that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Official action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. 1.136(a), and any fees required therefor are hereby authorized to be charged to **Deposit Account No. 024300**, Attorney Docket No. **034205.003**.

Respectfully submitted



Suzannah K. Sundby  
Registration No. 43,172

Date: 15 September 2010  
SMITH, GAMBRELL & RUSSELL, LLP  
1130 Connecticut Ave., NW, #1130  
Washington, D.C. 20036  
Telephone: (202) 263-4332  
Fax: (202) 263-4352  
ssundby@sgrlaw.com